



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2011-0224]

Applications of Bioassay for Radioiodine

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 2 to Regulatory Guide (RG) 8.20, "Applications of Bioassay for Iodine-125 and Iodine-131." The title of this regulatory guide has been changed to "Applications of Bioassay for Radioiodine." It describes methods and criteria acceptable to the NRC staff for the development and implementation of a bioassay program by licensees handling or processing unsealed materials containing Iodine-123 (I-123), Iodine-124 (I-124), Iodine-125 (I-125), Iodine-129 (I-129), and Iodine-131 (I-131), or a combination of these radionuclides.

ADDRESSES: Please refer to Docket ID **NRC-2011-0224** when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2011-0224**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may obtain publicly-available documents online in the NRC Library at

<http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. Revision 2 of RG 8.20 is available in ADAMS under Accession No. ML14064A060. The regulatory analysis may be found in ADAMS under Accession Number ML14064A058.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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SUPPLEMENTARY INFORMATION:

I. Introduction.

The NRC is issuing a revision to an existing guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information methods that are acceptable to the NRC staff for implementing specific parts of the agency's

regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

Revision 2 of RG 8.20 was issued with a temporary identification as draft regulatory guide (DG), DG-8050, entitled, “Applications for Bioassay for Radioiodine.” This guide was revised to achieve better alignment with: (1) Part 20 of Title 10 of the *Code of Federal Regulations* (10 CFR); and (2) the internal dose assessment methods recommended by the International Commission on Radiological Protection Publication 30, “Limits for Intakes of Radionuclides by Workers.” The content of the guide was also simplified by removing the appendixes of the previous version and including pertinent information in the main sections of the guide. Also, the title was changed because the guide now includes three more radioiodines (I-123, I-124, and I-129), in addition to the two radioiodines (I-125 and I-131) that were included in the previous version.

II. Additional Information.

This DG-8050 was published in the *Federal Register* on September 26, 2011, (76 FRN 59448) for a 60-day public comment period. The public comment period closed on November 22, 2011. Public comments on DG-8050 and the NRC staff’s responses to the public comments are available in ADAMS under Accession No. ML14064A061.

III. Congressional Review Act.

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting and Issue Finality.

This RG describes methods that the staff of the NRC considers acceptable for the development and implementation of bioassay programs for adult workers and for licensees handling or processing unsealed materials containing I-123, I-124, I-125, I-129, and I-131 or a combination of these radionuclides. Some of the applicants and licensees to whom this regulatory guide applies are protected by backfitting provisions in certain parts of 10 CFR Chapter I and/or the issue finality provisions in 10 CFR part 52.

Issuance of this RG does not constitute backfitting under 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, or 10 CFR 76.76, and is not inconsistent with any issue finality provisions in 10 CFR part 52. As discussed in the “Implementation” section of this regulatory guide, the NRC has no current intention to impose this regulatory guide on any licensees, including holders of licenses protected by the backfitting and issue finality provisions listed above. Applicants for the licenses listed above are not protected by any backfitting and issue finality provisions.

Backfitting and the issue finality provisions – with certain exclusions discussed below – are not intended to apply to every NRC action which substantially changes the expectations of current and future applicants. The exceptions to the general principle are applicable whenever an applicant references a part 52 license (e.g., an early site permit) and/or NRC’s regulatory approval (e.g., a design certification rule) with specified issue finality provisions. The staff does not, at this time, intend to impose the positions represented in this RG in a manner that is inconsistent with any part 52 issue finality provisions. If, in the future, the staff seeks to impose a position in the regulatory guide section in a manner which does not provide issue finality as

described in the applicable issue finality provision, then the staff must address the criteria for avoiding issue finality in that issue finality provision.

Dated at Rockville, Maryland, this 8th day of September, 2014.

For the Nuclear Regulatory Commission.

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